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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/305,390	05/05/1999	HIROAKI YAMAMOTO	06501/030001	2057

26161 7590 06/18/2003

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BOSTON, MA 02110

EXAMINER

HUTSON, RICHARD G

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/305,390	YAMAMOTO, HIROAKI	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7-10,12,14,23 and 28-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7,10,14,28,31-34,39,40 is/are allowed.
- 6) ☒ Claim(s) 8,9,23,29,30,35-38,41 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on 4/7/2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/305,390 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants addition of new claims 28-42, Paper No. 39, 4/7/2003, is acknowledged. Claims 7-10, 12, 14, and 23 are still at issue and are present for examination.

Applicants' argument filed on 4/7/2003, Paper No. 39, has been fully considered and has been deemed persuasive to overcome the previous 103 rejection.

### ***Amendments***

It is pointed out to applicants that the submitted copy of previously amended claim 7 is incorrect in that it recites "A method for producing a (S)-halo-3-hydroxybutyric acid ester..." and this should recite "A method for producing a (S)-4-halo-3-hydroxybutyric acid ester..."

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9, 23, 29, 30, 35-38, 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 (23, 35, 36, 41 and 42 dependent from) 9 (29, 30, 37 and 38 dependent from) are indefinite in the recitation "wherein said acetoacetyl-CoA reductase is **derived** from a microorganism belonging to the genus *Ralstonia*." It is unclear as to what applicants intend in the phrase "derived from". The specification discusses that not only naturally-occurring enzymes, but also variant enzymes having a modified amino acid sequence may be used in the claimed methods. As each of the above rejected claims depend from claim 7, which is drawn to the method of the invention using a naturally occurring acetoacetyl-CoA reductase, for each of the claims 8, 9, 23, 29, 30, 35-38, 41 and 42 to properly depend from claim 7, they must also be drawn to methods of use of naturally occurring acetoacetyl-CoA reductases. Thus, for the purpose of advancing prosecution the claims are interpreted as if they each recited "wherein said acetoacetyl-CoA reductase is from a microorganism belonging to the genus *Ralstonia*."

***Claim Rejections - 35 USC § 103***

The rejection of claims 7-10, 12, 14 and 23 under 35 U.S.C. 103(a) as being unpatentable over Matsuyama et al. (U.S. Patent No.: 5,559,030) in view of Peoples et al. (U.S. Patent No.: 5,229,279) or Summerville et al. (WO 93/02187) is hereby withdrawn.

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The original rejection was stated in the previous office action, Paper No. 12, 3/15/2000, and responses to applicants previous traversals can be found in Paper No. 18, 11/07/2000, Paper No. 22, 3/28/2001, Paper No. 27, 5/23/2001, and Paper No. 31, 3/12/2002. The rejection is withdrawn based on applicants arguments presented in Paper No. 38 and the declaration of Paper No. 39, April 7, 2003.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.  
Primary Examiner  
Art Unit 1652

rg  
June 16, 2003